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Are Binaural Beats Effective at Reducing Anxiety in Patients Undergoing Medical Intervention?

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not binaural beats are effective at reducing anxiety in patients undergoing medical intervention.

Study Design: Literature review of three English peer-reviewed studies, published on or after January 1, 2008.

Data Sources: Three randomized controlled trials (RCTs) were found using a search via the Cochrane Collaboration. These studies were selected based on relevance to binaural audio being used for reduction of anxiety and that the outcomes mattered to patients.

Outcomes Measured: The outcomes addressed in this study include patient anxiety levels pre- and post-operatively. Outcomes were measured using the Spielberger State-Trait Anxiety Inventory (STAI) and the Visual Analogue Scale (VAS).

Results: Isik et al found that at the pretest measurement of patients about to undergo dental surgery there was no significant difference (p=0.402) in anxiety felt in the experimental and control groups (t= -0,250, df 58, 95% CI of difference between means -1.323 to 1.030; difference= -0.147), however the second measurement performed after application of binaural audio to the experimental group demonstrated a significant difference (p= 0.006) in which the experimental group felt less anxiety (t= -2.843, df 58; 95% CI -3.061 to -0.532; difference = -1.797) (*British journal of oral & maxillofacial surgery*. 2017;55(6):571-574). Weiland et al found that out of the 169 patients undergoing emergency room procedures who completed the pre and post intervention anxiety self-assessments, there was a significant decrease (all P<0.001) in anxiety levels among patients exposed to binaural audio composition with state anxiety reduced 10-15% in moderately anxious emergency department patients (*Medical journal of Australia*. 2011;195(11):694-698). Wiwatwongwana et al found that patients in the binaural beats (BB) and musical intervention (MI) group showed a significant reduction of STAI state scores after music intervention compared with the control group (P<0.001); additionally, the difference between the BB and MI groups was not found to be significant (STAI-S score MI group -7.0, BB group -9.0, P = 0.085) (*Eye [london, England]*. 2016;30(11):1407-1414).

Conclusions: All three studies demonstrated that binaural beats are a beneficial and effective treatment to reduce preoperative anxiety. Implementing binaural beats may be a valuable nonpharmacologic treatment option for anxious preoperative patients when compared to toxic and addictive anxiolytics such as benzodiazepines.

Key words: binaural beats, anxiety, preoperative anxiety

INTRODUCTION

Anxiety is defined by the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), as the anticipation of future threat.[1] It is often associated with muscle tension and vigilance in preparation for future danger.[1] Patients experiencing preoperative anxiety would fall under specific phobia anxiety disorder in which one of the main symptoms is excessive and unreasonable desire to avoid the feared situation.[1,2] When exposed to the stimulus, immediate anxiolytic response will manifest, such as vasovagal fainting or near-fainting response that is exhibited by initial transient acceleration of heart rate and elevation of blood pressure.[1] Within the context of preoperative anxiety, those with this phobia will tend to avoid the situation that causes them anxiety, potentially leading to significant financial and health costs to the patient.[2,3]

The increasing costs associated with patient anxiety arises from patients failing to attend their appointment or procedure. A study of one community hospital in the U.S. placed the cost of annual no-shows around $3 million for that institution.[3] Those that are suffering from preoperative anxiety could become noncompliant due to their extreme fear. “In one case study, a 69-year old Caucasian man without any history of mental illness was transferred to an emergency department with dyspnea and tachycardia. He was later informed that he needed an emergency bypass operation due to being diagnosed with a non-ST elevation myocardial infarction (NSTEMI). When the patient was informed, he had a severe panic attack and due to his overwhelming fear, he refused the bypass operation.” [2]

According to a 2010 report from the CDC, in the U.S. alone, 28.6 million healthcare visits resulted in 48.3 million procedures or surgeries.[3] Approximately 60%-80% of patients admitted to hospitals for surgery will experience preoperative anxiety[4], which can influence patient recovery, as well as the intensity of post-operative pain.[4,5] In effect, a higher level of

preoperative anxiety will result in not only a greater need for postoperative analgesia, but also a higher dosage of intravenous anesthetics at induction and during maintenance.[4,5] Studies have also found that higher levels of preoperative anxiety lengthened hospital stays.[4,5]

Moderate or severe anxiety may require intervention with medication to reduce distress.[6] First-line treatment is benzodiazepines, with midazolam being the most strongly supported benzodiazepine in clinical trials.[6] While benzodiazepines may help with the patient's anxiety, studies have shown that patients who have used a benzodiazepine in the six months prior to surgery are associated with increased short and long term mortality, as well as an increased rate of postoperative opioid consumption.[7]

Studies have shown that incorporating musical intervention, primarily auditory beat stimulation (ABS), is a promising new resource for manipulating cognitive processes, reducing anxiety levels, and enhancing mood states.[8] Musical interventions have also been proven to lower blood pressure and heart rate, however, those outcomes are beyond the scope of this paper.[9] Binaural beats (BB), one type of ABS[8], are particularly useful because they can influence the brain through the entrainment of brainwaves to reduce anxiety, as well as increase the pain threshold.[9] Binaural beats are generated with steady amplitudes and sine waves of slightly different frequencies presented to each ear separately, most commonly through stereophonic headphones.[8] Binaural beats are the result of the effect of a central interaction at the cochlear level[8] that likely occurs in the accessory, also known as the medial nucleus, of the superior olivary complex (SOC).[10] The accessory is the first nucleus in the classical ascending auditory pathway that receives bilateral input.[10] Brainstem neurons in the SOC are sensitive to phase shifts and will fire action potentials at a rate corresponding to the phase difference between both ears which generates the perception of a new frequency, a true binaural beat.[8] Incorporating

binaural beats instead of medication as a primary intervention in preoperative patients would not only be a low-cost option, but would greatly reduce their anxiety without worry of postoperative noncompliance, mortality, medication toxicity, or addiction.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not binaural beats are effective at reducing anxiety in patients undergoing medical intervention.

METHODS

The three studies analyzed in this review all met the following criteria: the studies are randomized controlled trials (RCTs), two of which were assessed using the Spielberger State-Trait Anxiety Inventory (STAI) and one using the Visual Analogue Scale (VAS). The population addressed in each study are those who experienced anxiety in the setting of a medical intervention taking place perioperatively. The interventions being used were binaural beat audio tones delivered to patients through stereophonic headphones. The comparisons used in these studies were binaural beats, binaural beats combined with music, electroacoustic music, field audio recording (nature sounds) with binaural beats, ambient sounds of the emergency department, and no audio. The outcomes measured were the anxiety level of patients before and after the intervention.

A detailed search of the Cochrane Collaboration database was completed by the author using the keywords “binaural beats”, “anxiety”, and “preoperative anxiety”. Articles were selected based on relevance to binaural audio being used for reduction of anxiety and the importance to patient-oriented outcomes. Inclusion criteria for article selection were that all articles were

printed in English and were published in peer-reviewed journals on or after January 1, 2008. Studies that were published prior to January 1, 2008 were excluded.

The summary of statistics reported or used include the p-values, mean change from baseline, and standard deviation. Table 1 shows the demographics and characteristics of included studies.

TABLE 1- DEMOGRAPHICS AND CHARACTERISTICS OF INCLUDED STUDIES

Study	Type	# of Pts	Age (yrs.)	Inclusion Criteria	Exclusion Criteria	W / D	Interventions
Weiland[11], 2011	RCT	170	35-69	Age ≥18; Classified as requiring emergency medical assessment within 30 minutes	Pts with hearing impairment, could not speak English, or were unable to give informed consent	1	STAI assessment prior to: control- no audio intervention; simulated ambient noise; electroacoustic musical composition; composed non-musical audio field recordings; or combination field audio with BB. 20 min later STAI reassessed
Wiwatwongwana[9], 2016	RCT	141		Pts dx with senile cataract and scheduled for phacoemulsification with intraocular lens implant under local anesthesia	Pts with hx of cataract surgery; BP>160/100mmHg; hearing problems, ear infections, hx of epilepsy	0	Local anesthetic applied to all pts followed by allocation to either: BB embedded music; music w/o BB; or earphones w/o music. BP and heart rate were recorded at beginning of operation and 20 mins after start time. STAI-S was only completed postoperatively
Isik[12], 2017	RCT	60	15-47	Pts with a fully impacted mandibular third molar tooth that required removal; being otherwise healthy	Pts with hx of psych or hearing disorders, epilepsy, or were taking antidepressants / anticonvulsants/or opioids	0	Local anesthetic monotherapy followed by 10 min wait before reassessing VAS vs. local anesthetic combined with listening to BB through stereo headphones for 10 min before reassessing VAS.

OUTCOMES MEASURED

Outcomes used for analysis include preoperative anxiety. Weiland et al[11] and Wiwatwongwana et al[9] used the Spielberger State-Trait Anxiety Inventory (STAI), while Isik et

al[12] used the Visual Analogue Scale (VAS). The STAI measures anxiety with the state subscale and the trait subscale. The State-Trait Anxiety Inventory is a 40-item self-report measure that contains 20 items measuring state (current) anxiety (STAI-S) and 20 items measuring trait (baseline) anxiety (STAI-T).[9] Scores for state and trait components range from 20 to 80, with a higher score corresponding to a higher level of anxiety.[11] The VAS was chosen for the Isik et al[12] study because it has been shown to be a valid way to evaluate dental anxiety. This scale is comprised of a 100mm horizontal line drawn on paper with the left end marked 'no anxiety at all' and the right end marked 'worst anxiety imaginable'. Patients are asked to make a mark indicating their level of anxiety on the line which is measured in millimeters.[12]

RESULTS

All three randomized controlled trials (RCTs) measured preoperative anxiety levels before and after the intervention was performed on patients that were selected based on the inclusion criteria in Table 1. The following results from the three studies presented below do not contain continuous or dichotomous data. As a result, the relative risk reduction (RRR); absolute risk reduction (ARR); relative benefit increase (RBI); absolute benefit increase (ABI); numbers needed to treat (NNT); and numbers needed to harm (NNH) could not be calculated.

Weiland et al[11] conducted a randomized control trial (RCT) of 169 patients $\geq$18 years old that were classified as category 3 (urgent) according to the Australasian Triage Scale (ATS), meaning that the patients required medical assessment within 30 minutes. After each patient had their initial medical assessment and gave consent to participate in the study, they were given the STAI to assess anxiety levels. A computer-generated randomized sequence was used to select groups. Patients were split into five groups[11] as follows: the control group - headphones only and no soundtrack intervention; reconstructed ambient noise simulating emergency department (ED)

noise, but free of clear verbalizations; electroacoustic musical composition; composed non-musical audio field recordings; and combination of audio field recordings with embedded binaural beats. To capture the sounds of the ED, a condenser microphone was used to record sounds of air conditioning, fluorescent lights, telephones, computers, medical equipment, and later footsteps were added.[11] The electroacoustic musical composition consisted of melodic and percussive instruments that were created using a software based music processing program. Audio field recordings included nature sounds such as birds, frogs, water, crickets, etc. The binaural beats used were constructed "using two digital sine wave generators at 200 Hz and 210 Hz."[11] The headphones used were semi-professional headphones covered with disposable sanitary covers for each patient, and each was connected to an iPod. Patients were assessed after 20 minutes using the STAI, and data was analyzed using Statistical Package for the Social Sciences (SPSS) version 15.0 using an intention-to-treat approach. "Demographic data were analyzed using the Fisher exact test for 2 × 2 cross-tabulations and the independent samples t-test for interval data."[11] The data was analyzed using repeated measures analysis of variance (ANOVA) as a way to compare anxiety levels for each of the five groups "after accounting for baseline differences."[11] Alpha was set at 0.05 which indicates a 5% risk of concluding that a difference exists when there is no actual difference. There were 170 total patients recruited that were split into 34 patients (n=34) in each of the five groups. Of the 170 patients, only 1 did not complete the post-intervention STAI in the electro-acoustic composition group, leaving 169 patients (n=169) that completed the post-intervention anxiety self-assessment. There was a significant effect shown between "time and intervention ($F_{(4,164)}$=6.28; P<0.001)"[11] indicating a change over time in some, but not all the intervention groups. It is clear that based on the p value ($p<0.001$) of the audio field recordings alone and the audio field recordings with the binaural

beats ($p<0.001$), they were both significant at reducing anxiety levels, but there was not a difference between the two.

TABLE 2. Comparison of STAI scores before and after intervention[α]

Intervention	Pre	Post	Absolute Difference from Control (95% CI)	P-Value
Control (headphones only)	43.7 (14.2)	43.7 (16.4)	N/A	N/A
Audio Field Recordings	42.2 (13.9)	34.6 (9.6)	9.1 (-0.1 to 10.8)	P<0.001
Audio Field Recordings + Binaural Beats	42.6 (10.9)	36.9 (11.1)	6.8 (-2.3 to 8.6)	P<0.001

[α] Data derived directly from Weiland et al[11]

Wiwatwongwana et al[9] conducted a randomized control trial (RCT) on 141 patients who were diagnosed with senile cataracts that were scheduled for phacoemulsification with intraocular lens (IOL) implantation under local anesthesia. Patients were put in groups that were randomized via Random Allocation Software; the binaural beat group (BB), the plain musical intervention group (MI), and the control group (earphones with no music). Both the patient and researcher were blinded to allocation until the administration of interventions. The binaural beats were composed with a Self-Hypnosis and Relaxation Machine version 2.4, with the tones set at 109 Hz and 209 Hz. The musical arrangements included relaxing melodies, tones, rhythms, and natural sounds such as waterfalls, birds, ocean, river, and forest sounds. An iPod was used with canal headphones that were placed into the patients ears 10 minutes before the start of the operation. The control group wore headphones connected to an iPod without music. Blood pressure and heart rate were both recorded at the beginning of the operation, as well as 20 minutes after the start of the operation. Each group contained 47 patients (n=47) and each was required to provide 90% power at the 5% two-sided level. Statistical analyses were done using

Epi Info for Windows Version 3.5.1 and STATA version 11. The univariate analyses between the three groups (STAI-scores, blood pressure, heart rate) were performed with the p-value $\leq$0.05 being considered statistically significant. Post-operatively, the STAI-S scores in the MI and BB groups significantly decreased compared to the control group (P<0.001). Although there was not a significant difference between the BB and MI group (-9.0 vs -7.0; p=0.085), the BB group did show a slightly larger decrease in STAI-S score. Although heart rate a measure not being evaluated in this paper, it should be mentioned that after the 20-minute mark, the heart rate in the BB group was significantly lower compared to the control group (P<0.004) and the MI group (P<0.050).

Table 3. Comparison of Mean (SD) and P-Value Difference in Pre and Post STAI-S scores[α]

	Control (n=47)	MI (n=44)	BB (n=44)	Control vs. MI	Control vs. BB	MI vs. BB
Mean (SD)	-2.9 (4.4)	-7.0 (4.8)	-9.0 (4.2)	----	----	----
P-Value	----	----	----	<0.001	<0.001	0.085
CI	95%	95%	95%	----	----	----

[α] Data derived directly from Wiwatwongwana et al[9]

Isik et al[12] conducted a randomized control trial (RCT) on 60 volunteers undergoing removal of a fully impacted mandibular third molar tooth. Patients were divided into two groups of 30 (n=30): experimental (binaural beats) and control (no music). The randomization was done by tossing a coin. The control group consisted of 22 women and 8 men whose mean age range was 28 (15-47 years) and the experimental group consisted of 20 women and 10 men whose mean age was 24 (18-35 years). The binaural beats were produced by software running on a mobile device with 200 Hz in the left ear and 209.3 Hz in the right ear; additionally, they were pure frequencies, meaning there was no other background music or sounds. The patients were permitted to adjust the volume to their preference. Their anxiety was recorded on the visual analogue scale (VAS). The first measurement prior to intervention showed no significant

difference (p=0.402) between the anxiety felt when comparing both the experimental and control groups (t= -0.250, df 58; 95% CI of the difference between means -1.323 to 1.030; difference = -0.147). The second measurement, taken post-intervention, however, revealed a significant difference between both groups (p=0.006) with the experimental group showing less anxiety (t= -2.843, df 58; 95% CI -3.061 to -0.532; difference = -1.797). The analyses on the first and second measurements in the experimental group (t=7.258; df 29; 95% CI for difference of means 1.278 to 2.282; difference between means = 1.780) showed a significant decrease in anxiety (p<0.001), while the control group showed no difference (p=0.625) between first and second measurement (t=0.494, df 29; 95% CI for difference of means -0.408 to 0.668; difference between means = 0.130).

Table 4. Mean (SD) VAS score and P-Value comparison between experimental and control groups pre and post intervention[α]

Measurement	First (pre)	Second (post)	First(pre) P-Value	Second(post) P-Value	Total P-Value	CI
Experimental	5.37 (2.12)	3.59 (2.23)	----	----	<0.001	95%
Control	5.52 (2.42)	5.39 (2.65)	----	----	0.625	95%
Experimental + Control	----	----	p=0.402	p=0.006	----	95%

[α] Data derived directly from Isik et al[12]

DISCUSSION

Overall, these three studies show that binaural beat intervention can significantly decrease preoperative anxiety levels in patients. The implementation of binaural beats as either a primary or complementary treatment can keep costs of treatment lower, as well as defer pharmacological treatment that, as stated previously, can cause increased rates of postoperative mortality, an increased rate of postoperative opioid consumption which can lead to opioid addiction, and lastly help with patient compliance.[4,5]

In the Weiland et al[11] study, it was found that although binaural beats and audio field recordings both showed significant decrease in anxiety ($p<0.001$), binaural beats did not provide additional anxiety reduction over audio field recordings alone. This raises the concern that binaural beats might not be as effective in the emergency department setting as in a quiet preoperative setting.[11] It is also possible that the lack of experience of the researchers could have potentially resulted in improper delivery of interventions. The long length of the STAI survey (40 questions) could also limit its clinical utility in a fast-paced ED setting.

In the Wiwatwongwana et al[9] study, it is clear that BB's are effective at reducing anxiety levels. Although there was not a big difference between the BB and MI, (-9.0 vs -7.0; $p=0.085$), the BB showed a slightly larger decrease in the STAI-S score. The differences between the BB and MI vs the control, however, showed a significant difference in both comparisons (control vs MI $p<0.001$; control vs BB $p<0.001$). This proves that adding these complementary therapies could be very helpful in reducing preoperative anxieties. Several factors could have been standardized to make the results more uniform, such as: the cataract surgeries were performed by different surgeons, the deficiency of hearing was self-reported by the patients and not objectively tested, and in the first 5 minutes, the initial frequency of 20 Hz is a beta frequency, which causes an arousal state as opposed to the relaxed state of an alpha frequency, or 10 Hz.[9]

In the Isik et al[12] study, there were no previous studies on the use of binaural beats in dental surgeries, and as there were no guidelines for which frequency to use, the researchers used the alpha frequency of 9.3 Hz which has been shown to produce a relaxing effect.[9] In the results of this study, it is evident that the first and second VAS measurements in the experimental group showed a significant difference in anxiety reduction ($p<0.001$) while the control group showed no difference at all ($p=0.625$).

CONCLUSIONS

Yes, binaural beats are effective at reducing anxiety in patients undergoing medical intervention.[9,11-12] However, further studies should be done with more consistent variables to give researchers a better understanding of how the use of binaural beats would be most effective. Each of these studies used different frequencies of binaural beats, but it would be beneficial to use standardized frequency models in all subsequent studies. Another variable that would improve with standardization is a consistent time interval that the patient is exposed to the intervention. While all the studies mentioned above proved that binaural beats are effective, it would be valuable to know how long prior to the surgery the intervention should be applied so as to be most efficacious in reduction of the patient's anxiety levels. The scale at which anxiety is measured should also be uniform across all studies for purposes of data comparison. Additionally, it was concluded that the 40 question STAI might not be as efficient in an ED setting, so it may be beneficial to find one scale that can be used in every kind of medical setting. Binaural beats may not be an appropriate therapy for every single patient with anxiety, because we must consider those who are hearing impaired, or young children, who would have a harder time focusing on the intervention. Further studies need to be done with binaural beats to be able to implement them on a larger scale, but it has been proven that they are successful at reducing anxiety. Applying this low-cost, non-pharmacologic, safe, and effective treatment could be a breakthrough technology in healthcare as a primary or complementary therapy in reducing patients' preoperative anxiety.

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